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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,042	04/27/2001	Filippo Belardelli	B-4161 618742-8	1462

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,042	BELARDELLI ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *26-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-25, filed 10/28/03, is acknowledged. Applicant argues, "In view of the expenses that would be imposed upon the Applicants by multiple patents, it is believed that restriction requirements should be issued only when absolutely necessary; and the Applicants respectfully request withdrawal of the outstanding restriction requirement."

These arguments are not found persuasive for the following reasons. Applicant is advised that search burden and not expense is the condition under which restriction is required.

Regarding claim rejoinder, where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all elected product claims are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 26-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-25 read on the elected invention and are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) Claims 1 and 21 are grammatically unclear in the recitation of "since the initial culture thereof." For examination purposes it is assumed that the phrase is intended to indicate that IFN is employed in the claimed method of cell culture from the beginning of said culture.

B) Claim 2 is indefinite as it is unclear what differentiates the method of Claim 2 from the method of Claim 1. Claim 1 recites a method wherein IFN is employed in the claimed method of cell culture from the beginning of said culture whereas dependent Claim 2 recites a method wherein the step of employing IFN in the culture is "carried out within 3 days of culture." If Claim 2 is intended to be broader in scope than Claim 1 in cannot depend on Claim 1.

C) Claims 3 and 4 are vague and indefinite as they recite a method employing "any synthetic type I IFN" as the term is not defined in the specification.

D) Claims 5-12 are vague and indefinite as they recite a method employing a "final concentration", however the claims fail to recite what the "final concentration" consists of.

E) Claims 13-14 and 22 are vague and indefinite as they recite a method employing a "cell growth factor" as the term is not defined in the specification.

F) Claims 19-20 are vague and indefinite as they recite a method employing a "maturation agent" as the term is not defined in the specification.

G) The phrase "which can be" in Claim 22 renders the claim indefinite because it is unclear whether the limitations

following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

H) Claims 17-18 are vague and indefinite as they recite a method employing a "250-1000 U/ml" as the term is not defined in the specification. It is unclear how "U" differs from "IU".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention, but not included in the claims are not enabled by the disclosure. The instant claims recite a method of deriving dendritic cells which is disclosed in the specification as "a rapid generation of partially mature and highly functional DCs, suitable as cellular adjuvants in prophylactic as well as therapeutic vaccination of animal and human beings" (page 5). Accordingly the claimed method must result in "highly functional DCs". The specification discloses that the use of 100 IU/ml of IFN in the claimed culture method failed to result in "any significant upregulation" of costimulatory molecules (page 28) and that the resulting DCs "elicited a poor proliferative response" in MLRs (page 31). *Only* cultures employing 1000 IU/ml IFN resulted in functional DCs. Accordingly, the use of 1000 IU/ml IFN in the claimed method would be considered essential to the instant invention. Likewise, *all* disclosed cultures employed 500 IU/ml GM-CSF. Thus, the use of 500 IU/ml GM-CSF in the claimed method would also be considered essential to the instant invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bartholome et al. (1999).

Bartholome et al. teaches a process for deriving dendritic cells from mononuclear cells in culture, wherein said cells are peripheral blood mononuclear cells (PBMC) or CD14+ monocytes, comprising the step of putting in contact said mononuclear cells with type I interferon (IFN) at a final concentration greater than 100 IU/ml, since the initial culture thereof. The method further employs 1000 IU/m of IFNβ (within the claimed ranges of Claims 5-12 and 22-25) as well as the cell growth factor GM-CSF and the maturation agent IL-4 (see particularly page 472, column 1, *Generation of DC from peripheral blood of healthy donors*, and page 473, column 2).

The reference clearly anticipates the claimed invention.

9. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Paquette et al. (1998).

Paquette et al. teaches a process for deriving dendritic cells from mononuclear cells in culture, wherein said cells are peripheral blood mononuclear cells (PBMC) or CD14+ monocytes, comprising the step of putting in contact said mononuclear cells with type I interferon (IFN) at a final concentration greater than 100 IU/ml, since the initial culture thereof. The method further employs 200-5000 IU/m of IFNα (comprising the claimed ranges of Claims 5-12 and 22-25) as well as the cell growth factor GM-CSF and the maturation agent IL-4 (see particularly page 359, column 1, paragraph 2, and page 361, Figure 3).

The reference clearly anticipates the claimed invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

1/20/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER